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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/777,078

02/13/2004

Robert I. Connelly

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4130

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7590

09/15/2010

ROYLANCE, ABRAMS, BERDO & GOODMAN, L.L.P.

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SUITE 600

WASHINGTON,, DC 20036

EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/15/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,078	Applicant(s) CONNELLY ET AL.	
	Examiner MATTHEW F. DESANTO	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Idriss (USPN 4838887).

3. Idriss discloses an infusion pump, with a housing, a reservoir containing a supply of said fluid, a first flow channel in fluid communication with said reservoir, a delivery cannula and a resealable port. (Figure 3, 5B and entire reference)

4. Claims 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Reinicke et al. (USPN 4715852).

Reinicke et al. discloses a medical infusion pump comprising a housing (20), a reservoir (30) under pressure by a spring element, a first and second flow channel (42,48), a delivery cannula (126) in fluid communication with the first and second flow channel and a resealable port (28) (Figure 1-4, 9, 10 and entire reference).

5. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris (USPN 4,548,607).

Harris discloses a medical infusion pump comprising a housing, a reservoir fluidly connected to a delivery cannula (12), a primary restrictor (20), a bolus restrictor channel

with a bolus button (21) and a bolus exit channel connected to a spring check valve (81) (Figure 1-4, 9, 10 and entire reference).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratoska et al. (USPN 5445616), and further in view of Pike et al. (USPN 5009251) and further in view of Harris (USPN 4548607).

Kratoska et al. discloses a medical pump with a housing, a reservoir, a delivery cannula, a spring, a resealable port and a flow regulator, but fails to describe the flow regulator in detail. (Figure 1,2 and entire reference)

Pike et al. discloses a fluid flow controller used for regulating the fluid flow in medical devices, wherein the fluid regulator comprises many channels and the channels have a plurality of sections and a plurality of nodes. The regulator has a selectable knob, which determines the rate of fluid control by closing fluid channels throughout the device. (Figure 3,4,5,8, 9 and entire reference)

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the disclosed invention of Kratoska et al. with the fluid regulator of Pike et al., because Kratoska et al. discloses a flow regulator (30), "which can be any type of flow restriction device," (Kratoska - Column 3, line 64-67) with his claimed

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invention, therefore allowing one of ordinary skill in the art to make a obvious modification to combine the teachings of Pike et al.'s flow regulator with the disclosed invention of Kratoska et al. The reason for using Pike et al. disclosed invention is because it is cheap and very accurate in controlling the amount of liquid infused. (Pike - Column 1, lines 32-46).

For claims 22-24

Kratoska et al. and Pike et al. disclosed the claimed invention except for the bolus button.

Harris discloses a bolus button connected to restrictor channel and a bolus exit channel and wherein the bolus the bolus restrictor channel further comprises a check valve and a flow restrictor channel.

At the time of the invention it would have been obvious to combine Kratoska et al. and Pike et al. with Harris because Harris teaches a manually actuated micro pump which is convenient to operate and economical to manufacture, therefore adding the bolus button to the disclosed invention would allow for an easy and convenient way to administer a large dose of the drug to the patient.

Terminal Disclaimer

8. The terminal disclaimer filed on 06/29/2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of USPN 6,702,779 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

9. Applicant's arguments filed 06/29/2010 have been fully considered but they are not persuasive.

10. The examiner respectfully disagrees with the interpretation of the claims and the interpretation of the prior art. The examiner feels that the applicant is reading limitations from the specification into the claims and suggests adding the specific interpretation of the claim language from the specification.

11. With regards to the Idriss rejection the examiner respectfully disagrees with the claim interpretation of a restrictor channel and in fluid communication. The examiner feels that the prior art shows this since the restrictor channel in claim 15 can be anything that restricts flow by means of channel, therefore a valve structure, or a narrowing section, and a filter could read on this limitation. The examiner uses the broadest reasonable interpretation and thus uses this line of reasoning for fluid communication, since the examiner interprets the septum in fluid communication with the reservoir, and delivery cannula, since fluid can flow from the port to the delivery cannula.

12. With regards to Reinicke, the examiner has withdrawn claims 1-14, but maintains the rejection based on claims 15-20 because of the broadest reasonable interpretation of fluid communication.

13. With regards to Harris, the applicant argues limitations that are not in the claims. For example applicant argues the claim requires two parallel channels between the reservoir and the delivery cannula but fails to see this limitation in the claim. The

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examiner feels applicant is reading limitations into the claim and therefore gives the claims the broadest reasonable interpretation.

14. With regards to the 103 rejection, the examiner feels that applicant is arguing limitations from the specification and drawings and not positively recited in the claim. The examiner feels that the broadest reasonable interpretation must be given to the claims and therefore maintains his rejections (except for Reinicke claims 1-14) since applicant argued language that was not directly expressed in the claim.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MATTHEW F. DESANTO whose telephone number is (571)272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

Matthew DeSanto
/Matthew F DeSanto/
Primary Examiner, Art Unit 3763